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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4

345 COURTLAND STREET, N.E.
ATLANTA, GEORGIA 30365

JUN 07 1996

4WD-SSRB

EXPRESS MAIL

Mr. R. Vyas
Corporate Manager
Environmental Remediation
Witco Corporation
One American Lane
Greenwich, CT 06831-2559

SUBJ.: LeMoyne Superfund Site

Dear Mr. Vyas:

The United States Environmental Protection Agency (EPA) has reviewed Witco's February 29, 1996, submittal that addresses the Draft Feasibility Study Report for the Stauffer (LeMoyne Plant) Superfund Site in Axis, Alabama, Operable Unit #2. EPA's Health Risk Superfund Technical Support Center (STSC) has also reviewed the submittal, focusing specifically on the additional information regarding the toxicity of thiocyanates, literature review, and Witco's proposal for an alternate RfD.

EPA agrees with Witco that the animal studies on thiocyanate toxicity and an RfD based on animal data would not be inferior to one based on the human health data. However, we do not agree with Witco on the proposed NOAEL of 128 mg/kg/day for a number of reasons. A detailed analysis of your submittal, prepared by EPA's STSC is enclosed with this letter. One noteworthy reason for our disagreement is that other studies, specifically the Phillbrick study, identified a LOAEL of 67 mg/kg/day for thyroid effect. This values is almost half of the 128 mg/kg/day dose from the Lijinsky study. STSC, in their analysis, calculated an RfD using the 128 mg/kg/day as a **LOAEL** and by applying uncertainty factors. The calculated RfD was 4E-2mg/kg/day. The confidence in the principal study is low, the confidence in the database is medium to low; therefore, EPA's confidence in the calculated RfD is also low.

Although the Witco submittal was informative in its literature research, it did not present to the Agency a strong or confident case to deviate from the current cyanide based RfD or the groundwater remediation goal of 200 ug/L thiocyanate.

I look forward to discussing these issues with you on the June 10, 1996 conference call. If you have any questions on this matter, please call me at 404-347-3555 extension 6234.

Sincerely,

Joanne Benante

Joanne Benante
Remedial Project Manager
South Superfund Remedial Branch

cc: R. Dulcey
J. Nortz
J. Zarzycki
M. Tehrani
E. Newman
J. Dollarhide
H. Choudhury

ENCLOSURE

MEMORANDUM

DATE: May 13, 1996

SUBJECT: Review of thiocyanate RfD proposed by Witco Corporation for the Stauffer Chemical site in Region IV and the Halby Chemical site in Region III.

FROM: Joan S. Dollarhide
NCEA

THRU: Harlal Choudhury
Director
Superfund Health Risk Technical Support Center

TO: Joanne Benante
U.S. EPA, Region IV

Eric Newman
U.S. EPA, Region III

This memo transmits my review and comments on the new RfD for thiocyanate developed by ERM on behalf of Witco Corporation for both the Stauffer Chemical site in Region IV and the Halby Chemical site in Region III. Their proposed RfD is based on additional information obtained from the authors of Lijinsky and Kovatch (1989) in which the long-term effects of thiocyanate were tested in F344 rats. First, I will address Witco comments on the human studies, then I will address their proposed RfD.

Human vs. Animal Data

As Witco noted, in our original 1993 assessment of thiocyanate, we concluded that, although thyroid toxicity, fatigue, anemia, and dry skin were adverse effects in humans, there appeared to be insufficient information to quantitate these effects. However, in 1995, Witco submitted an RfD based on a 1940 review of human studies. This RfD was based on a superficial assessment of the human data and several of its assumptions were not supported by the available data. Yet, Witco claimed that an RfD based on animal data was inferior to one based on human data. Thus, at the request of Region 4, in 1995 we developed an RfD based on the human data that was more appropriate than that developed by Witco.

As Witco's 1996 report acknowledges, there are problems with the human database

including poor characterization of dose and bias in the measurement of blood pressure; within our office, we had many discussions on how the human data could best be used. If Witco has reevaluated the human data and is satisfied that, in this case, an RfD based on the animal data will not be inferior to one based on the human data, then I will agree.

Proposed RfD

The ideal animal study on which to base an RfD is a well conducted, chronic bioassay which identifies both a NOAEL and a LOAEL. A study which only identifies a LOAEL can be used as the basis of an RfD because we know that the NOAEL must be at some point between 0 and the LOAEL. We deal with this uncertainty by adding an additional uncertainty factor. However, a study which only identifies a NOAEL is more problematic because there is no way of knowing where the true threshold lies. Thus, studies which identify "freestanding NOAELs" are often rejected as the basis of an RfD, particularly if other studies in the database indicate that dose levels at or below the freestanding NOAEL are LOAELs.

As ERM notes, the only chronic study conducted on thiocyanate was published by Lijinsky and Kovatch in 1989. In this study, F344 rats received thiocyanate in drinking water for a lifetime. Doses were estimated at 75 mg/kg/day for males and 128 mg/kg/day for females. The authors only reported the carcinogenicity results, and for this reason, we originally concluded that the study was inadequate for a quantitative assessment. ERM contacted Dr. Lijinsky who reported that, in fact, a complete histopathology including noncancer lesions had been conducted. Based on the additional data, ERM concluded that the only dose tested was a NOAEL. However, Dr. Lijinsky had only forwarded the data for treated animals to ERM, not the data for control animals. Thus, as far as I can tell, no one has done a complete analysis of results in treated animals compared to controls and ERM's conclusions are not based on fact.

When I evaluated the Lijinsky data, two findings suggested that the only dose tested may be a LOAEL rather than a NOAEL. First, there is an increase of thyroid hyperplasia in the female treated rats compared with the control female rats (7/20 treated females compared with 3/20). Although this incidence just falls short of statistical significance, it has biological significance because it is demonstrating a known toxic effect of thiocyanate. Also, there was a statistically significant increase in atrophy of pancreatic acini in the treated females compared to control females (9/20 treated females compared with 3/20 control females). However, I do not know if this elevation has biological significance.

I am also concerned about the high incidence of kidney and liver lesions in the control animals. There was almost 100% incidence of kidney nephropathy and liver effects including bile duct hyperplasia in both control males and females. This does not seem normal and may indicate that the animals' health was compromised by other factors. It might be interesting to see the historical control incidence for these lesions.

If Lijinsky and Kovatch (1989) does, in fact, identify a freestanding NOAEL as suggested

by ERM, I would be reluctant to recommend it as the basis for an RfD because several other studies identified LOAELs at similar or lower doses than that tested by Lijinsky. In particular, Phillbrick et al. 1979, which is an 11.5 month study, identified a LOAEL of 67 mg/kg/day for thyroid effects, almost half the dose tested by Lijinsky.

By considering the dose level in Lijinsky to be a LOAEL, this study could serve as the basis on an RfD. Applying a total uncertainty factor of 3,000 (10 for use of a LOAEL, 10 for extrapolation from animals, 10 for human sensitive subpopulations, 3 for database deficiencies) to the LOAEL of 128 mg/kg/day results in a provisional RfD of 4E-2 mg/kg/day. Confidence in the principal study is low. Only one dose level was tested and there were a small number of animals. Although there was a complete histopathology and all potential target organs were evaluated, the authors did not perform an analysis and statistical comparison of noncancer effects in treated animals vs controls. Confidence in the database is medium-to-low. Most of the human and animal studies focused on only one endpoint. The database lacks a well conducted chronic study, lacks a chronic study in a second species, lacks multigenerational studies, and lacks studies of reproductive effects resulting from exposure to males. Reflecting the low confidence in the principal study and the database, the confidence in the RfD is low.